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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,776	08/23/2000	John Burczak	DEX-0079	2610

7590

03/17/2003

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 03/17/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

# Advisory Action

Application No.  
09/622,776

Applicant(s)  
Burczak et al

Examiner  
Ungar

Art Unit  
1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jan 21, 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☒ The period for reply expires three months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: Claim 16 is drawn to subject matter of rejected/canceled claim 13. Entry of the amendment would require further consideration in order to determine whether to reapply the rejection under 35 USC 103 to the claims.

3. ☐ Applicant's reply has overcome the following rejection(s):  
\_\_\_\_\_  
\_\_\_\_\_
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
see attached  
\_\_\_\_\_
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: none

Claim(s) objected to: none

Claim(s) rejected: 10-12

Claim(s) withdrawn from consideration: none

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

SUSAN UNGAR, Ph.D.  
PRIMARY EXAMINER

Art Unit: 1642

1. If the Amendment were to be entered, claims 10-12 would remain rejected under 35 USC 112 first paragraph for the reasons previously set forth in Paper No. 9, Section 3, pages 2-5.

Applicant argues that (a) neither reference suggests a standard deviation of 1 ng/ml of PLA2 as neither of these references provide the data required to accurately calculate standard deviation, (b') just because a marker is taught to be useful in diagnosing other types of cancer, does not mean that it cannot be useful in diagnosing previously undisclosed types of cancer and batteries of other tests including physical examination are used by physicians to arrive at an accurate diagnosis, (c) in order to advance prosecution, Applicants have amended the claims to clarify the methods.

The argument has been considered but has not been found persuasive because (a') it is clear from the Range of Variability that the standard deviation is about 1 ng/ml, (b') for the reasons of record, Applicant does not teach how to diagnose ovarian or testicular cancer with the invention as claimed and further, Applicant is arguing limitations not recited in the claims as currently constituted, (c') the amendment has not been entered and the claims have not been so amended.

2. If the Amendment were to be entered, claims 10-12 would remain rejected under 35 USC 112 first paragraph for the reasons previously set forth in paper No. 9, Section 4, pages 5-6.

Applicant argues that claim 10 has been canceled. The argument has been considered but has not been found persuasive because the amendment has not been entered and claim 10 has not been canceled.

SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER



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